

Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Cardiovascular and Renal Drugs Advisory Committee (CDER)
March 1, 2010
DRAFT AGENDA

8:00 a.m.	Call to Order Introduction of Committee	Emil Paganini, M.D. Acting Chair, CRDAC
	Conflict of Interest Statement	Minh Doan, Pharm.D. Acting, Designated Federal Official

The committee will discuss biologics license application (BLA) 125,288, from Bristol-Myers Squibb, for belatacept injectable, to be used in patients with kidney transplants to prevent rejection of the transplanted kidney.

8:10 a.m.	FDA Introductory Remarks	Edward Cox, M.D., M.P.H. Director, Office of Antimicrobial Products (OAP), CDER
8:20 a.m.	<u>Sponsor Presentations</u>	
9:50 a.m.	Questions from the Committee to Bristol-Myers Squibb	
10:10 a.m.	BREAK	
10:25 a.m.	<u>FDA Presentations</u>	
11:50 a.m.	Questions from the Committee to FDA	
12:15 p.m.	LUNCH	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Questions from the Committee to FDA and Bristol-Myers Squibb	
2:20 p.m.	Charge to the Committee	
2:30 p.m.	Committee Discussion of Questions/Vote	
4:00 p.m.	BREAK	
4:15 p.m.	Continuation of Committee Discussion of Questions/Vote	
5:00 p.m.	Adjourn	